

§ 886.5928

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: “Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.”

[62 FR 30988, June 6, 1997]

§ 886.5933 [Reserved]

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.

888.1 Scope.

888.3 Effective dates of requirement for premarket approval.

888.5 Resurfacing technique.

888.6 Degree of constraint.

888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

888.1100 Arthroscope.

888.1240 AC-powered dynamometer.

888.1250 Nonpowered dynamometer.

888.1500 Goniometer.

888.1520 Nonpowered goniometer.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

888.3000 Bone cap.

888.3010 Bone fixation cerclage.

888.3015 Bone heterograft.

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888.3020 Intramedullary fixation rod.

888.3025 Passive tendon prosthesis.

888.3027 Polymethylmethacrylate (PMMA) bone cement.

888.3030 Single/multiple component metallic bone fixation appliances and accessories.

888.3040 Smooth or threaded metallic bone fixation fastener.

888.3045 Resorbable calcium salt bone void filler device.

888.3050 Spinal interlaminar fixation orthosis.

888.3060 Spinal intervertebral body fixation orthosis.

888.3070 Pedicle screw spinal system.

888.3080 Intervertebral body fusion device.

888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.

888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

888.3150 Elbow joint metal/polymer constrained cemented prosthesis.

888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

888.3200 Finger joint metal/metal constrained uncemented prosthesis.

888.3210 Finger joint metal/metal constrained cemented prosthesis.

888.3220 Finger joint metal/polymer constrained cemented prosthesis.

888.3230 Finger joint polymer constrained prosthesis.

888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.

888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.

888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

888.3380 Hip joint femoral (hemi-hip) trunion-bearing metal/polyacetal cemented prosthesis.